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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/453,801	12/03/99	CHATTERJEE	S 1954-287

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HM12/0327

EXAMINER

LEFFERS JR, G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/453,801	Applicant(s) Chatterjee, et al.
	Examiner Gerald G. Leffers Jr.	Group Art Unit 1636

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-33 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-33 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

... SEE OFFICE ACTION ON THE FOLLOWING PAGES ...

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to methods of stably transferring DNA into multi-potential hematopoietic stem cells in G0 phase with AAV vectors, classified in class 435, subclass 456.
- II. Claims 24-25, drawn to recombinant AAV vectors, classified in class 435, subclass 320.1.
- III. Claims 26-33, drawn to stably transduced hematopoietic stem cells residing in the G0 phase of the cell cycle, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the AAV vectors of Group II can be used to transduce other cell types or hematopoietic stem cells at different stages of the cell cycle.

Inventions of Group I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

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claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the methods of Group I (infection of cells residing at G0 phase in the cell cycle with a recombinant AAV vector) can be practiced with cells which are not hematopoietic stem cells. Also, the stably transduced stem cells of Group III can be produced by the utilization of other recombinant vectors by transduction followed by arrest in the G0 phase or by other vectors (e.g. lentiviral vectors, however inefficiently).

The inventions of Group II and Group III are chemically, biologically, structurally and functionally distinct from each other and thus one does not render the other obvious. The AAV vectors of Group II are not required to make the stably transduced hematopoietic stem cells of Group III (the stably transduced stem cells can be transduced by other vectors or by electroporation prior to arrest in the G0 phase), and the transduced stem cells are not required for the production of the AAV vectors of Group II (which can be produced in suitable packaging cell lines). Therefore, the inventions of the two groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Dr. Rob Schwartzman, can be reached on (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

AGZ
G. Leffers, Jr.
Patent Examiner
Art Unit 1636


ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER

March 25, 2001